K062846

510(k) Summary of Safety and Effectiveness

OCT 13 2006

Applicant Name and Address: Collagen Matrix, Inc.
509 Commerce Street
Franklin Lakes, New Jersey 07417

Contact Person: Peggy Hansen, RAC
Sr. Director, Clinical, Regulatory, and Quality Assurance
Tel: (201) 405-1477
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Date of Summary: September 19, 2006

Device Common Name: Collagen Dental Membrane

Device Trade Name: Collagen Dental Membrane III

Device Classification Name: Bone Grafting Material
Class II
872.3930
LYC

Predicate Device(s): Collagen Dental Membrane, K011695

Description of the Device

Collagen Dental Membrane III is a white, nonfriable, conformable, resorbable, membrane matrix engineered from highly purified type I collagen derived from bovine Achilles tendon. It is flexible and conforms to the contours of the defect site. Collagen Dental Membrane III is supplied sterile, non-pyrogenic, in various sizes, and for single use only.

Intended Use

Collagen Dental Membrane III is intended for use in dental surgery procedures as a material for placement in the area of dental implant, bone defect or ridge reconstruction to aid in wound healing post dental surgery.

Summary/Comparison of Technical Characteristics

Collagen Dental Membrane III and its predicate have similar technological characteristics. In particular, the Collagen Dental Membrane III and its predicate are similar with respect to intended use, material, form, sizes, thickness, physical integrity, permeability and conformability.

Safety

A Collagen Dental Membrane III equivalent has been evaluated by a number of tests to assess its safety/biocompatibility. The device passed all applicable FDA Blue Book Memorandum G95-1and ISO 10993-1 testing for the biological evaluation of medical devices.

Conclusion

The results of the *in vitro* product characterization studies show that the device modification of the Collagen Dental Membrane III is safe and substantially equivalent to the original device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville, Maryland 20850

OCT 10 2007

Ms. Peggy Hansen, RAC
Senior Director, Clinical, Regulatory and Quality Assurance
Collagen Matrix, Incorporated
509 Commerce Street
Franklin Lakes, New Jersey 07417

Re: K062846
Trade Name: Collagen Dental Membrane III
Regulation Number: 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: 2
Product Code: NPL
Dated: September 20, 2006
Received: September 25, 2006

Dear Ms. Hansen:

This letter corrects our substantially equivalent letter of October 13, 2006.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Protecting and Promoting Public Health

K062846

Indications for Use

510(k) Number (if known): K062846

Device Name: Collagen Dental Membrane III

Indications for Use:

Collagen Dental Membrane III is intended for use in oral surgical procedures as a resorbable material for placement in the area of dental implant, bone defect, or ridge augmentation to aid in wound healing.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Kei Mulay for MSP

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K062846